K122497

510(k) Summary

OCT 15 2012

Submitter: Medical Designs, LLC
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Date Prepared: August 15, 2012

Trade Name: Asfora Anterior Cervical Plate System

Classification: Class II
Spinal intervertebral body fixation orthosis
21 CFR §888.3060

Product Code: KWQ

Predicate Device(s): The subject device is substantially equivalent to the following devices:

- Synthes Anterior CSLP System (Synthes, K030866)
- Trinica Select™ Anterior Cervical Plate System (Centerpulse Spine-Tech, K022344), currently marketed by Zimmer Spine

Device Description: The Asfora Anterior Cervical Plate System is composed of plates of varying lengths to accommodate surgical procedures from one to four levels. The plates are designed for application to the anterior aspect of the cervical spine and have manual locking mechanisms to reduce the potential for screws to back out of the vertebral body. The screws are provided in diameters from 4.0mm to 5.0mm (rescue) and lengths from 14mm to 16mm

Intended Use: The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical spine fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Substantial Equivalence:

Similarities to Predicate Devices			
Parameter	**Medical Designs Cervical Plate System (Subject Device)**	**Synthes Anterior CSLP System (K030866)**	**Centerpulse Spine-Tech Trinica Select™ Anterior Cervical Plate System (K022344)**
Intended Use	The cervical plate system is intended for use in anterior interbody screw fixation of the cervical spine.	same	same
Principle of Operation	Fixation is achieved by inserting bone screws through openings in the plate into the vertebral bodies of the cervical spine.	same	same
System Components	• Plates (1-4 levels) • Locking Screws Screw locking mechanisms	same	same
Material	Titanium (Ti-6A1-4V alloy per ASTM F136)	same (Implant grade commercially pure titanium)	same (Ti-6A1-4V alloy per ASTM F136)
Sterility	Non-Sterile. Hospital steam sterilization recommended.	same	same

Differences from Predicate Devices			
Parameter	**Medical Designs Cervical Plate System (Subject Device)**	**Synthes Anterior CSLP System (K030866)**	**Centerpulse Spine-Tech Trinica Select™ Anterior Cervical Plate System (K022344)**
Indications for Use Statement	The Asfora The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical spine fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion	The Synthes Anterior CSLP System is intended for anterior screw fixation to the cervical spine (C2-C7) for the following indications: 1. Spondylolisthesis 2. Fracture 3. Spinal stenosis 4. Tumor Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).	The Trinica/Trinica Select Anterior Cervical Plate System is intended for anterior interbody screw fixation of the surgical spine at levels C2-T1. The system is indicated for use in the temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin of the disc confirmed by patient history and radiographic studies), trauma (including fractures), tumors, deformity (defines as kyphosis, lordosis, or scoliosis), pseudoarthrosis, and/or failed previous fusions.
Plate Lengths	23-93 mm	23-109 mm	22-92mm
Locking Screw Size	• Ø 4.0 mm 14-16 mm lengths	• Ø 4.0-4.5mm 12-20 mm length	• Ø 4.2-4.6 mm 12-20 mm length

Screw Locking Mechanisms	Locking rings are preassembled onto the plate and include anti-rotational locking features and safety locking tabs that engage to prevent the screws from backing out.	The system includes expansionhead screws and locking screws which lock to the plate.	Locking caps are preassembled onto the plate and are designed with tabs that prevent bone screws from backing out.
Additional Screw Types	Temporary Fixation : Ø 3.5 mm, 14 mm Rescue: Ø 5.0 mm, 14 mm and Ø 5.0 mm, 16 mm	none	Threaded temporary fixation pins, sizes not available

Functional and Safety Testing:

Mechanical testing was conducted, in accordance with *Guidance for Industry and FDA Staff Spinal System 510(k)s* and safety testing using ASTM F 1717 to ensure the device performs according to specification, to verify that the device is able to withstand clinical loading and maintain mechanical integrity, and is suited for its intended purpose. Testing included static and dynamic compression bending, and static torsion.

Conclusion:

Medical Designs, LLC considers the Asfora Anterior Cervical Plate System to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 15 2012

Medical Designs, LLC
% Ms. Kristi Vondra
Vice President of Operations
6709 South Minnesota Avenue, Suite 204
Sioux Falls, South Dakota 57108-2593

Re: K122497
Trade/Device Name: Asfora Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: August 15, 2012
Received: August 16, 2012

Dear Ms. Vondra:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K122497

4.0 Indications for Use Statement

Device Name: Asfora Anterior Cervical Plate System

The Asfora Anterior Cervical Plate System is intended to provide temporary stabilization to the anterior spine during the development of cervical fusions (C2-T1) for the following indications: degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K122497